Knowledge Acquisition Report
NCI Common Data Elements Model

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Session Topic: Task Hierarchies for Common Data Elements Business Actors

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Type of Session

_____ Interview _____ Task Analysis _____ Scenario Analysis
_____ Concept Analysis _____ Observation _____ Structured Interview
__**X**__ Other: Role and Task Hierarchy Analysis

Documentation:

Previous Knowledge Acquisition Efforts with:
- Southwest Oncology Group
- Radiation Therapy Oncology Group
- Cancer and Leukemia Group B
- University of California, Irvine
- IknowMed, Inc.
- Lombardi Cancer Center
- CDE Reviewers at Cancer Therapy Evaluation Program
- CDE Steering Committee
- Oracle, Corp.

CDE Dictionary web site
(http://cii-server5.nci.nih.gov:8080/pls/cde_public/cde_java.show)

Report Summary

This report represents the initial steps in building a model for the use of Common Data Elements (CDEs) in the cancer clinical trials domain. It contains descriptions of the individuals and groups (business actors) involved with CDEs. The report also contains task hierarchies for each business actor. The report concludes with a brief description of the next steps in Knowledge Acquisition for the project. The information in this report is subject to update as additional knowledge is gathered during the project.

Overview of the Common Data Elements Effort

One of the National Cancer Institute's (NCI) goals is to employ computer technology to improve the cancer clinical trials process. Computer technology can be used to reduce paperwork, simplify protocol administration, improve communication, and provide patients with accessible, timely data.

The Common Data Elements (CDE) Project supports NCI's computer technology implementation goal. NCI intends to create a standardized, computer-readable terminology specific to cancer research. Adoption and use of this terminology is intended to provide the cancer research community with the following benefits:

- Consistent and efficient collection of data
- Uniform reporting
- Data analysis across clinical trials using common variables
- Elimination of redundancy and unnecessary data collection
- Data mining opportunities

NCI has formed CDE Committees to begin creating sets of common data elements specific to cancer types. Each committee includes representatives from NCI and from various cooperative groups. Physicians, statisticians, research nurses, and clinical research assistants have participated in CDE development on these committees.

Business Actors

The term "business actors" is derived from Object Oriented analysis and refers to the individuals and groups primarily involved in set of high level business activities. For the purposes of this report, the business activities in question are the development, maintenance and use of Common Data Elements.

The business actors for Common Data Elements fall into three organizational groups:

- National Cancer Institute (NCI)
- Cancer Centers and Other Cooperative Groups
- Other

Figure 1 depicts the business actors in each group. Note that one business actor, CDE Committee, falls into two organizational groups. That is because CDE Committees are comprised of individuals from both NCI and Cooperative Groups.

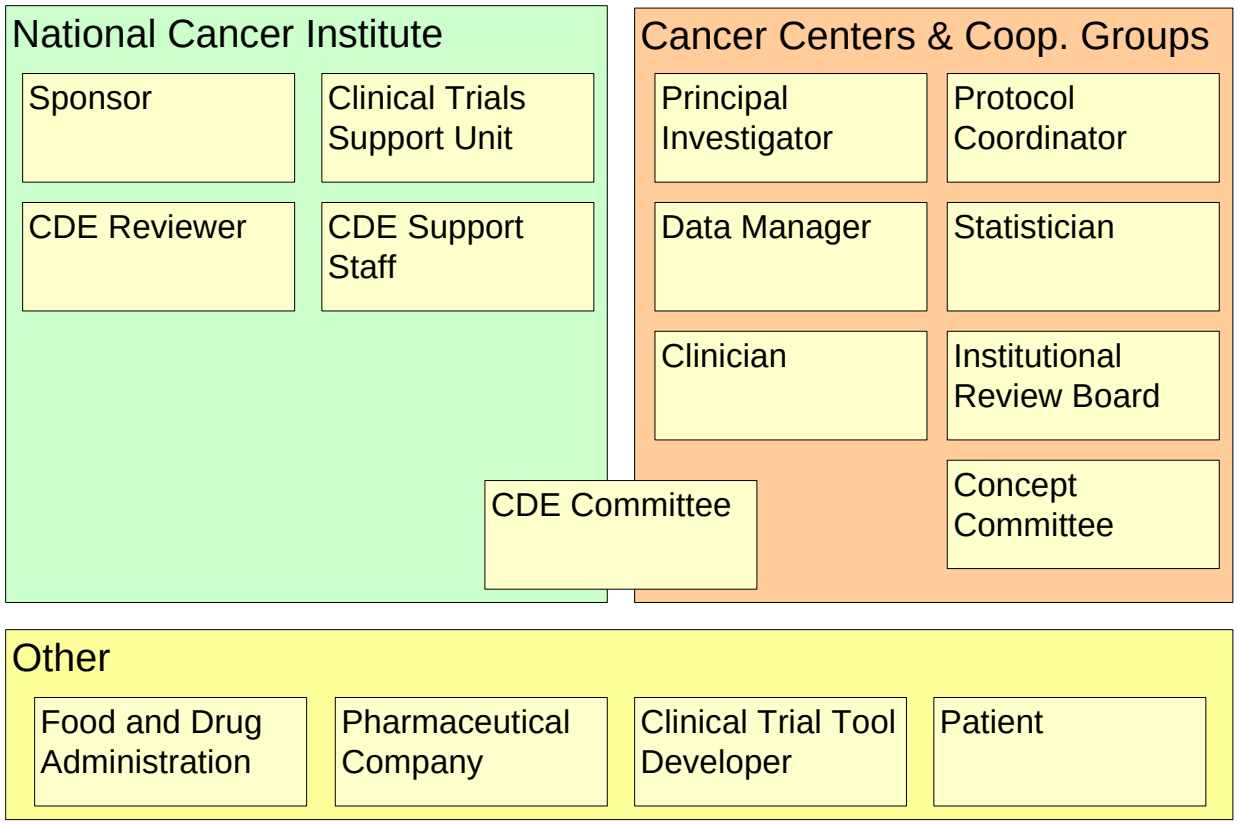

Figure 1: CDE Business Actors by Organizational Group

The following sections briefly describe each of the business actors and outline the hierarchy of tasks for each.

Sponsor

An organization that solicits, approves, and pays for a clinical trial. The sponsor for a clinical trial will typically be a division of NCI, a pharmaceutical company, or a cancer center. NCI divisions will sponsor most trials involving Common Data Elements. The clinical trial sponsor will usually handle regulatory filings for the clinical trial.

Sponsor Task Hierarchy

1.0 Plan drug development
    1.1 Review pre-clinical findings
    1.2 Plan clinical trials
2.0 Complete regulatory filings
    2.1 File Investigational New Drug applications with FDA
    2.2 File New Drug applications with FDA
    2.3 File Form 1572s with FDA
    2.4 Submit protocols to FDA
    2.5 Submit protocol amendments to FDA

3.0 Solicit clinical trials
    3.1 A. Send mass solicitations to cancer researchers
    3.2 B. Contact cancer researchers individually
4.0 Approve clinical trials
    4.1 Review letters of intent/concepts/proposals
    4.2 Approve letters of intent/concepts/proposals
    4.3 Review protocols
    4.4 Approve protocols
5.0 Fund clinical trials
    5.1 Identify funding mechanisms
    5.2 Evaluate funding requests
    5.3 Release funds
    5.4 Track funding
6.0 Monitor clinical trials
    6.1 Monitor accruals
    6.2 Monitor adverse events
    6.3 Monitor treatment results
    6.4 Review protocol amendments
    6.5 Approve protocol amendments
7.0 Evaluate clinical trial results
    7.1 Review findings
    7.2 Assess findings' impact on next phase of drug development

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CDE Reviewer

An individual at the National Cancer Institute who evaluates whether submitted clinical trial documents (protocols, case report forms) comply with common data element terminology.

CDE Reviewer Task Hierarchy

1.0 Maintain familiarity with Common Data Elements
    1.1 Review new Common Data Elements
    1.2 Review Common Data Element changes
    1.3 Review proposed changes to Common Data Element structure and attributes
2.0 Validate case report forms
    2.1 Verify that submitted case report form items are CDE compliant
    2.2 Communicate required changes to case report form submitters
    2.3 Identify potential new Common Data Elements from CRFs
    2.4 Identify potential changes to Common Data Elements from CRFs
3.0 Educate users about Common Data Elements
    3.1 Provide informal training to CDE users
    3.2 Respond to inquiries about Common Data Elements
    3.3 Contact CDE users to discuss potential problems

Clinical Trials Support Unit (CTSU)

An NCI-sponsored consortium with the missions of: (a) improving cross-group patient accruals, (b) streamlining clinical trial data entry/collection, and (c) standardizing membership rosters and IRB approvals. The consortium consists of Oracle Corp., Westat, Inc., and the Coalition of National Cancer Cooperative Groups.

Clinical Trials Support Unit Task Hierarchy

1.0 Support cross-group clinical trial Patient enrollment
- 1.1 Promote cross-group enrollment
- 1.2 Maintain CTSU web site
- 1.3 Process cross-group enrollment data gathered on web site
- 1.4 Report cross-group enrollment results

2.0 Support remote data capture for clinical trials
- 2.1 Promote remote data capture
- 2.2 Maintain remote capture data management system
- 2.3 Render case report forms in data management system
- 2.4 Synchronize data management system with Common Data Elements

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CDE Support Staff

A group of individuals knowledgeable about common data elements and cancer research who help CDE committees and NCI CDE Reviewers carry out their tasks. CDE Support Staff may organize CDE Committee meetings, gather information for CDE Reviewers, and update information in the CDE database.

CDE Support Staff Task Hierarchy

1.0 Assist CDE Committee
- 1.1 Schedule CDE Committee meetings
- 1.2 Organize materials prior to CDE Committee meetings
- 1.3 Publish notes from CDE Committee meetings
- 1.4 Conduct research for CDE Committees
- 1.5 Organize output from CDE Committees
- 1.6 Manage releases of newly published CDEs

2.0 Assist CDE Reviewers
- 2.1 Research CDE problems
- 2.2 Research potential new CDEs
- 2.3 Research potential changes to CDEs

CDE Committee

A committee convened by NCI, consisting of experts in clinical trials for a particular type of cancer (breast, prostate, GI, etc.). With assistance from NCI personnel and CDE Support Staff, the committee defines a commonly used set of terminology for data relating to that type of cancer (Common Data Elements). This committee also evaluates proposed new elements for inclusion in the terminology.

CDE Committee Task Hierarchy

1.0 Develop new Common Data Elements for a disease
- 1.1 Assemble resources
- 1.2 Sort through resources
- 1.3 Organize data elements
- 1.4 Reduce data elements
- 1.5 Link data elements to existing standards
- 1.6 Revise data elements
- 1.7 Finalize Common Data Elements
- 1.8 Publish Common Data Elements
- 1.9 Publicize Common Data Elements

2.0 Evaluate proposed changes to Common Data Elements
- 2.1 Review proposed changes
- 2.2 Estimate impact of proposed changes
- 2.3 Approve/reject proposed changes
- 2.4 Publish any revisions to Common Data Elements

Principal Investigator

A physician with the primary responsibility for the development and submission of a clinical trial protocol and the conduct of the resulting clinical trial.

Principal Investigator Task Hierarchy

1.0 Secure Clinical Trial Funding and Approval
- 1.1 Submit LOI/Concept to Concept Committee
- 1.2 Write Letter of Intent/Concept
- 1.3 Submit Letter of Intent/Concept to Sponsor
- 1.4 Revise Letter of Intent/Concept
- 1.5 Write Protocol
- 1.6 Submit Protocol to Sponsor
- 1.7 Revise Protocol
- 1.8 Submit Protocol to IRB

2.0 Conduct Clinical Trials
- 2.1 Prepare for clinical trial audits
- 2.2 Secure drugs for clinical trials
- 2.3 Prepare instructions for clinical trials
- 2.4 Enroll clinical trial patients

2.5 Treat clinical trial patients
2.6 Collect clinical trial data
2.7 Respond to sponsor inquiries
2.8 Report adverse events
2.9 Close clinical trial
2.10 Report findings to Sponsor
3.0 Publish Clinical Trial Results
4.0 Stay abreast of cancer research issues
4.1 Read medical journals
4.2 Communicate with colleagues
4.3 Attend seminars
4.4 Attend training
5.0 Prepare reports
5.1 Provide safety reporting
5.2 Report protocol variations
5.3 Report protocol violations
5.4 Provide annual reports
5.5 Report protocol status changes

Data Manager

An individual at a cooperative group or cancer center who designs clinical trial case report forms and manages the data returned on those forms.

Data Manager Task Hierarchy

1.0 Develop case report forms
1.1 Evaluate protocol data collection needs
1.1.1 Read protocol
1.1.2 Consult with Statistician about data analysis needs
1.2 Design case report form
1.2.1 Identify sources for case report form elements
1.2.2 Select existing case report form items
1.2.3 Create new case report form items
1.2.4 Define case report form layout
1.3 Respond to inquiries about case report forms
1.4 Revise case report forms
1.5 Review and edit completed case report forms
2.0 Manage collected clinical trial data
2.1 Verify that clinical trial data have been collected
2.2 Evaluate collected clinical trial data
2.3 Resolve data problems
3.0 Evaluate data management policy changes

Clinician

A physician, research nurse, physician's assistant, or technician who treats patients using the treatment regimen prescribed in a clinical trial protocol and who collects the required data.

Clinician Task Hierarchy

1.0 Enroll Patients in clinical trials
- 1.1 Identify potential clinical trial Patients
- 1.2 Screen Patients for eligibility
  - 1.2.1 Examine Patients
  - 1.2.2 Administer tests required for eligibility screening
  - 1.2.3 Educate Patients about clinical trials
- 1.3 Secure informed consent from Patients

2.0 Treat clinical trial Patients
- 2.1 Schedule treatment sessions
- 2.2 Educate Patients about treatment
  - 2.2.1 Create calendars for Patients
  - 2.2.2 Create instructions for Patients
- 2.3 Help Patients get to treatment sessions
- 2.4 Provide treatment to Patients
  - 2.4.1 Conduct physical exams
  - 2.4.2 Administer meds
  - 2.4.3 Carry out procedures
- 2.5 Monitor Patient progress

3.0 Manage clinical trial data
- 3.1 Collect data from Patients
  - 3.1.1 Conduct physical exams
  - 3.1.2 Carry out procedures
  - 3.1.3 Conduct tests
  - 3.1.4 Draw and process labs
  - 3.1.5 Complete source documents
- 3.2 Prepare for data collection
  - 3.2.1 Develop flowsheets and worksheets
  - 3.2.2 Develop order sheets
- 3.3 Collect source documents
- 3.4 Review source documents
- 3.5 Complete case report forms

4.0 Prepare reports
- 4.1 Provide safety reporting
- 4.2 Report protocol variations
- 4.3 Report protocol violations
- 4.4 Provide annual reports
- 4.5 Report Form 1572 modifications

4.6 Report protocol status changes

5.0 Manage budgets and contracts
- 5.1 Evaluate protocols
- 5.2 Create budgets
- 5.3 Submit budgets
- 5.4 Monitor budgets
- 5.5 Review contracts

Protocol Coordinator

An individual at a cooperative group or cancer center who coordinates the development of a clinical trial protocol and who may in fact write part of the protocol or adapt parts of it from previous protocol documents.

Protocol Coordinator Task Hierarchy

1.0 Develop clinical trial letters of intent/concepts
- 1.1 Prepare letters of intent/concepts for review
- 1.2 Meet with Principal Investigator
- 1.3 Meet with Concept Committee
- 1.4 Prepare letters of intent/concepts for Sponsor submission
- 1.5 Coordinate revisions to letters of intent/concepts document

2.0 Develop protocols
- 2.1 Develop new boilerplate items for protocols
- 2.2 Modify boilerplate items for protocols
- 2.3 Gather boilerplate for a protocol submission
- 2.4 Pull sections from previous protocol documents for re-use
- 2.5 Communicate with protocol development participants about protocol
  - 2.5.1 A. Communicate with Principal Investigators
  - 2.5.2 B. Communicate with Data Managers
  - 2.5.3 C. Communicate with Concept Committees
  - 2.5.4 D. Communicate with Statisticians
  - 2.5.5 E. Communicate with Institutional Review Boards
  - 2.5.6 F. Communicate with Protocol Coordinators from cooperating groups/ cancer centers
- 2.6 Draft new items for protocol document
- 2.7 Incorporate new items into protocol document
- 2.8 Coordinate revisions to protocol
- 2.9 Coordinate amendments to protocol

Statistician

An individual at a cooperative group or cancer center who determines the statistical design required for a clinical trial and who analyzes clinical trial data once it has been collected and returned.

Statistician Task Hierarchy

1.0 Provide statistical expertise for study design
    1.1 Develop experimental design
    1.2 Develop analysis plan
    1.3 Identify accrual needs for ancillary studies
    1.4 Determine cell sizes
    1.5 Provide input on case report form design
2.0 Analyze study data
    2.1 Validate collected data
    2.2 Resolve data errors
    2.3 Perform data analysis
    2.4 Draw conclusions
    2.5 Report clinical trial results to Principal Investigator

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Institutional Review Board

A committee for a cancer research institution that must review and approve all clinical trial activity at that institution. Institutions with large numbers of clinical trials usually have multiple Institutional Review Boards.

Institutional Review Board Task Hierarchy

1.0 Approve clinical trial for the institution
    1.1 Review protocol document
    1.2 Review data collection and case report forms
    1.3 Conduct risk/benefit analysis
        1.3.1 Evaluate risks to human subjects of research
        1.3.2 Evaluate to the research institution's interests
        1.3.3 Evaluate potential scientific benefits from the research
    1.4 Request more information from the Principal Investigator
    1.5 Request changes
        1.5.1 Request changes to the protocol
        1.5.2 Request changes to the case report forms
    1.6 Approve/reject the protocol document and case report forms
2.0 Reassess the clinical trial
    2.1 Review changes to protocol
    2.2 Review new information that has arisen
    2.3 Revise risk/benefit analysis

Concept Committee

A committee at a cooperative group or cancer center that evaluates possible clinical trial topics and determines which ones should be pursued for development into protocols.

Concept Committee Task Hierarchy

1.0 Identify clinical trial concepts to purse for protocol development
    1.1 Review concept summaries
    1.2 Request additional information from Principal Investigators
    1.3 Evaluate concept summaries
    1.4 Prioritize clinical trial concepts

Food and Drug Administration (FDA)

A federal organization that regulates all aspects of food and drug production, including the development and conduct of clinical trials.

Food and Drug Administration Task Hierarchy

1.0 Approve Investigational New Drug Applications
2.0 Approve New Drug Applications
3.0 Approve Form 1572 Submissions
4.0 Approve clinical trial protocols
    4.1 Approve new clinical trial protocols
    4.2 Require changes to clinical trial protocols
    4.3 Approve clinical trial protocol revisions
    4.4 Approve clinical trial protocol amendments
5.0 Enforce federal drug regulations

Pharmaceutical Company

An organization that investigates, develops and markets chemotherapeutic and chemopreventive agents.

Pharmaceutical Company Task Hierarchy

1.0 Investigate new drugs
    1.1 File patents
    1.2 Conduct pre-clinical research
    1.3 Identify promising new drugs
2.0 Develop new drugs
    2.1 Promote agents to cancer researchers
        2.1.1 Attend conferences
        2.1.2 Visit cancer centers

2.1.3 Call on cancer researchers
2.2 Complete regulatory filings
2.3 Sponsor clinical trials
2.4 Provide agents for clinical trials sponsored by others
2.5 Market drugs

Clinical Trial Tool Developer

A software developer attempting to create and implement information technology to support some aspect of clinical trial development or management.

Clinical Trial Tool Developer Task Hierarchy

1.0 Identify market/target users in the clinical trials domain
2.0 Develop user requirements
2.1 Identify user needs
2.2 Identify features desired by users
2.3 Evaluate the users' environment
2.4 Generate testable user requirements
3.0 Design solution
3.1 Identify available technologies
3.2 Identify available data
3.3 Identify constraints
3.4 Conduct trade studies
3.5 Draft a system architecture
4.0 Market solution
5.0 Develop solution
6.0 Test solution
7.0 Implement solution

Patient

An individual enrolled in a clinical trial investigating the treatment or prevention of cancer. The patient must meet specific eligibility criteria defined in the clinical trial protocol.

Patient Task Hierarchy

1.0 Enroll in Clinical Trial
1.1 Locate Clinical Trial
1.1.1 A. Ask Physician about Clinical Trials
1.1.2 B. Search the Internet for Clinical Trials
1.1.3 C. Call cancer organization (NCI, ACS) to ask about Clinical Trials
1.2 Participate in Eligibility Screening
1.2.1 Undergo eligibility screening examination
1.2.2 Answer eligibility screening questions
1.2.3 Undergo eligibility screening tests
1.3 Give Informed Consent
2.0 Undergo Treatment

2.1 Schedule treatment sessions
2.2 Attend treatment sessions
2.3 Report problems
2.4 Undergo progress tests
2.5 Self-administer medications

3.0 Provide Information for Clinical Trial
3.1 Answer clinical trial progress/results questions
3.2 Provide samples
3.3 Undergo clinical trial progress/results tests
3.4 Complete questionnaires

4.0 Maintain Quality of Life
4.1 Gather information
4.2 Manage pain and side effects
4.3 Secure emotional support
4.4 Secure family/household support

Future Knowledge Acquisition

In order to build an object-oriented model of Common Data Elements use, next steps include drafting Business Use Cases and a Business Object Model. Domain experts should validate the information in this report, the Use Cases and the Object Model to ensure that the domain is represented accurately. Therefore, knowledge acquisition sessions should be held with representatives of selected business actor groups. Likely domain experts would include:

- Clinicians
- Data Managers
- Statisticians
- Protocol Coordinators
- CDE Reviewers
- CDE Support Staff